



Date: 28-Apr-2026

Dr. Somnath Roy
Senior consultant Medical Oncology
TATA Medical Centre
West Bengal, India, 700160

Protocol No.: D9106R00007

Protocol Title: A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Subject: IEC Dossier for submission

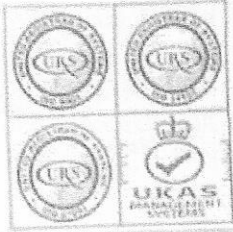
Dear Dr. Roy

At the outset, we would like to thank you for your continued cooperation.

On behalf of the Sponsor AstraZeneca and as the Contract Research Organization (CRO) conducting the study, we kindly request your assistance in submitting the below-mentioned study documents to the Institutional Ethics Committee for review and approval:

Please find enclosed here 01 set of hard copy of each document as requested for submission

S. No.	Table of Content
1.	Investigational Study Protocol Version 1.0 Dated 22-Dec-2024
2.	Consent Letter dated 31 Jan 2026.
3.	Declaration Letter dated 31 Jan 2026.
4.	Investigator Undertaking dated 16 Feb 2026.
5.	Informed Consent Document 5.1 English ICD version 1.0 dated 09-Mar-2026 5.2 Hindi ICD Version 1.0 dated 16-Mar-2026 5.3 Bengali ICD Version 1.0 dated 16-Mar-2026 5.4 Back Translated Hindi to English ICD Version 1.0 dated 16-Mar-2026 5.5 Back Translated Bengali to English ICD Version 1.0 dated 16-Mar-2026 5.6 Hindi ICD Translation and Back Translation Certificate Dated 16-Mar-2026 5.7 Bengali ICD Translation and Back Translation Certificate Dated 16-Mar-2026



CIN NO - U74900DL2009PTC194906

B-503-507 "NOIDA ONE",
SEC-62, NOIDA (UP)-201309
Ph: +91-120-3104633

6.	Prescribing Information sheet dated 09-Feb-2026.
7.	Final Case Report Form version 2.0 13-Feb-2026.
8.	Investigator Documents 8.1 Curriculum Vitae of Investigator signed on 02-Feb-2026 8.2 MRC of Investigator signed on 25-Apr-2025 Valid till 31-Dec-2026 8.3 GCP of Investigator signed on 25-Apr-2025 Valid till 22-Apr-2027 8.4 Curriculum Vitae of CO-I signed on 03-Dec-2025 8.5 MRC of CO-I Signed on 03-Dec-2025 Valid till 31-Dec-2026 8.6 GCP of CO-I signed on 03-Dec-2025

We would request you submit the documents to IRB/IEC and send us a copy of the IRB/IEC acknowledgement letter, if received.

We kindly request you to submit the above documents to your Institutional Ethics Committee at the earliest possible date and provide us with:

- Acknowledgement of submission (by signing the "acknowledgement section" herein)
- IRB/IEC review schedule (if available)
- Approval letter once obtained

Please share a scanned copy of the submission acknowledgement/approval and forward the original document to the CRO for our records. Should you have any queries or require clarification, please feel free to contact:

Sonali Kumari

sonali.kumari@tech-observer.com

Contact Number 9693924213



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We sincerely thank you for your support in initiating this important clinical study.
Yours sincerely,

Sonali Kumari

Clinical Trial Associate

For and on behalf of

Tech Observer India Pvt. Ltd.

Sonali Kumari
28-APR-26

I Acknowledge the Receipt of documents for IRB/IEC submission.

Receiver's Name:

Dr. Sonali Ruy

Designation:

Senior Consultant of Medical Oncology

Signature:

Sonali Ruy

Date:

05/5/26

OFFICE OF THE ATTORNEY GENERAL

STATE OF NEW YORK

The undersigned, being a duly qualified and sworn member of the bar of the State of New York, do hereby certify that the within and foregoing is a true and correct copy of the original as the same appears in the files of the Department of the Attorney General.

Very truly yours,

Notary Public

JOHN J. [illegible]

Notary Public

for the County of [illegible]

I AGREE TO BE BOUND BY THE DECISION OF THE COURT IN ANY CASE WHEREIN THE COURT MAY BE CALLED UPON TO ENFORCE THE SAME.

Notary Public

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Notary Public

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Notary Public

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Notary Public

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